The Nagoya Protocol and biosciences

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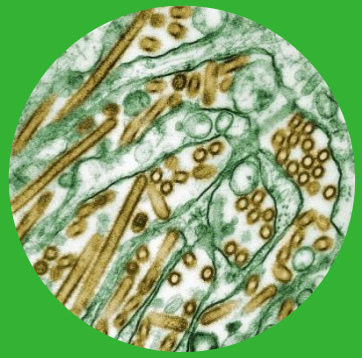
UNIVERSITY & RESEARCH

Centre for Genetic Resources, the Netherlands

The Nagoya Protocol and biosciences

- What is it about?
- How is it implemented in the EU and NL?
- What is considered ‘utilisation’?
- What to do as a user?



The Nagoya Protocol is about Access and Benefit Sharing (ABS)

- Access and Benefit-Sharing
  - regulation of access to genetic resources and associated traditional knowledge
  - sharing of benefits from the use of these between providers and users
- What does it mean?
  - you cannot always freely take and utilise ("access") genetic resources anymore, but may need permission from a government
- What forms of benefit-sharing exist?
  - monetary (e.g. royalties, up-front payments)
  - non-monetary (e.g. scientific co-operation, technology transfer, trainings)

ABS: from CBD to Nagoya Protocol

- Convention on Biological Diversity (CBD, 1993)
  - *genetic resources no longer considered 'heritage of mankind'*
  - *instead, all states have sovereign rights over their genetic resources*
  - *widely accepted (CBD has now 196 Parties)*

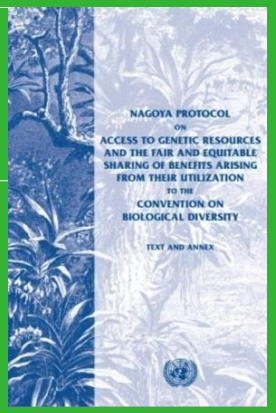
- National ABS legislations introduced
  - e.g. Philippines (1995), Costa Rica (1998), Brazil (2001)
    - *rules often unclear and complex*
    - *enforcement difficult*

- Nagoya Protocol (2014)
  - elaboration of the ABS provisions of the CBD
    - *provider countries to ensure clear and transparent procedures*
    - *compliance to ABS rules in provider countries to be monitored by the countries where the genetic resources are utilized*

The Nagoya Protocol

- Additional Protocol to the *Convention on Biological Diversity* (CBD, 1993)
- Objective
  - *"the fair and equitable sharing of the benefits arising from the utilization of genetic resources (...), thereby contributing to the conservation of biological diversity and the sustainable use of its components."*
- Entry into force: ***12 October 2014***
- Legally binding for countries that are Parties to the Protocol

The Nagoya Protocol



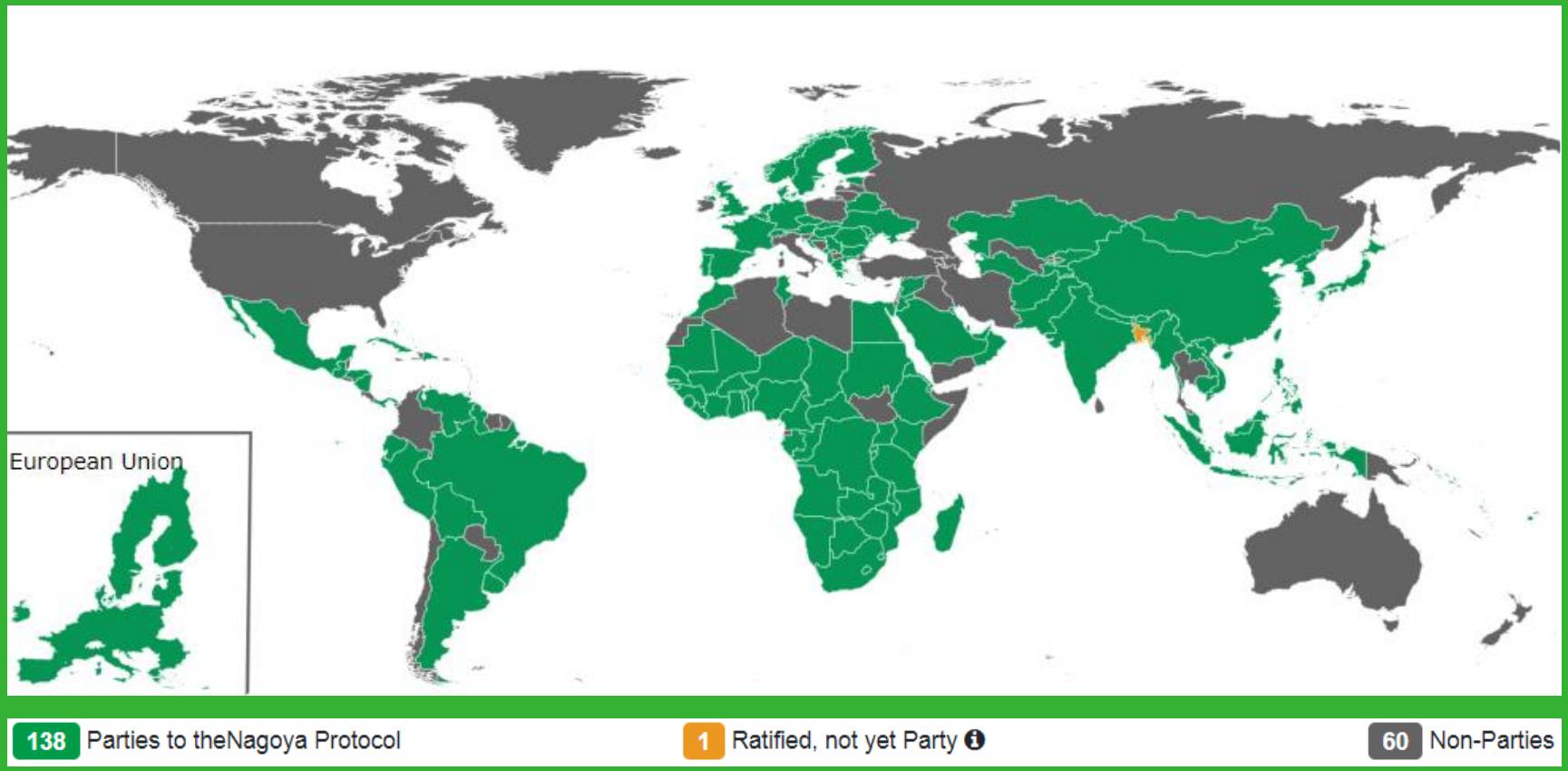
- Principles
  - Provider countries are to ensure clear and transparent procedures
  - Compliance to ABS rules in provider countries is to be monitored by the countries where the genetic resources are utilised
- Access to genetic resources on the basis of
  - Prior Informed Consent (PIC): permission by authorities of the country providing genetic resources
    - ➢ *unless otherwise determined by that country*
  - Mutually Agreed Terms (MAT): contract between provider and user

The Nagoya Protocol

- Access to genetic resources and the sharing of benefits arising from their utilisation
  - what are genetic resources?
    - *any material of plant, animal, microbial or other origin containing functional units of heredity, that is of actual or potential value*
    - except for human genetic resources
  - what is utilisation of genetic resources?
    - *to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology*
- Also provisions on access to derivates and traditional knowledge
- In the future also Digital Sequence Information (DSI)

Nagoya Protocol

ABS Clearing-House: https://absch.cbd.int/



(3 April 2023)

Bangladesh: as of 10 April 2023

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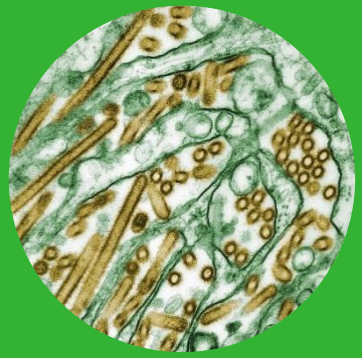

EU Regulation 511/2014 (EU ABS Regulation)

- Implements compliance aspects of the Nagoya Protocol in the EU
  - *only deals with compliance, not with access*
  - *access regulated at national level, not at EU level*
- Entry into force: **12 October 2014**
  - same date as entry into force of Nagoya Protocol
- Contains obligations for:
  - users of genetic resources and associated traditional knowledge in the EU
  - EU Member States
- Legally binding for all companies, institutions and individuals within the EU

EU ABS Regulation

- Applies to genetic resources
  - accessed from 12 October 2014 onwards
  - accessed from a country that is a Party to the Nagoya Protocol and has established access measures
  - utilised in R&D within the EU
- Does not apply when ABS is covered by a 'specialised international instrument'
  - International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)
  - Pandemic Influenza Preparedness Framework (PIP-framework)

National legislation in provider countries may go further than EU ABS Regulation

- Check ABS Clearing-House website, ask National Focal Point of the provider country

EU ABS Regulation

Obligations of users of genetic resources and associated traditional knowledge in the EU (Art. 4)

- to exercise 'due diligence' to ascertain that the genetic resources they utilise have been legally acquired, and that benefits are shared
- to utilise and transfer genetic resources in accordance with the MAT (Mutually Agreed Terms)
- therefore:
  - seek relevant ABS information (including permits and contracts)
  - keep ABS information for 20 years after end utilisation
  - transfer ABS information to subsequent users

Which information should be collected, kept and passed on?

- Internationally recognised certificate of compliance (IRCC), published on ABS Clearing-House website by provider country
  - *over 4500 IRCCs published*

OR

- Information/documents on:
  - date and place of access.
  - description of the genetic resource.
  - source from which the genetic resources was directly obtained.
  - rights and obligations relating to ABS (including those related to subsequent applications and commercialisations).
  - access permits (PIC and other), where applicable.
  - mutually agreed terms (MAT), including any benefit-sharing arrangements.

(EU Guidance section 3.5)

EU: important supporting documents

- Commission Implementing Regulation (EU) 2015/1866
  - entry into force: 9 November 2015
  - lays down more detailed rules on the implementation of certain articles of the EU ABS Regulation
    - *due diligence declarations*
    - *register of collections*
    - *best practices*
  - legally binding

- EU Guidance document
  - published in 2016, revised version published in 2021
  - provides more detailed information and practical examples on the scope and user obligations of the EU ABS Regulation
    - *e.g. collection management and taxonomy not in scope*
  - not legally binding; explains the EU ABS Regulation

National legislation NL

Nagoya Protocol (Implementation) Act (with Explanatory Memorandum, Regulation and Decrees)

- Implements Nagoya Protocol in NL
- Entry into force: 23 April 2016
- Competent National Authority (CNA):
  Ministry of Agriculture, Nature and Food Quality (LNV)
- Monitoring agency: Netherlands Food and Consumer Product Safety Authority (NVWA)
- National Focal Point (NFP):
  Centre for Genetic Resources, the Netherlands (CGN)
- Access to Dutch genetic resources not regulated: Prior Informed Consent (PIC) not needed

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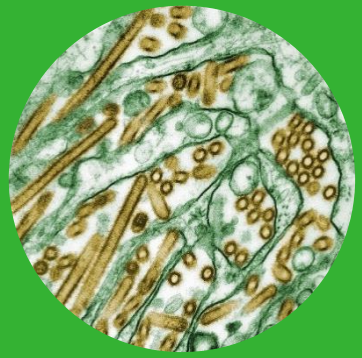

What is considered ‘utilisation’? (EU)

- ‘Utilisation’ = research and/or development (fundamental research, applied research, product development)
  - *if the activity creates new insight into characteristics of the genetic resource which is of (potential) benefit to the further process of product development, this is considered ‘utilisation’*
- EU ABS Regulation: utilisation within the EU
- Further explained in EU Guidance (published in 2016, revised in 2021)
  - Some important topics:
    - Large-scale screening
    - Service providers
    - Laboratory strains
    - Derivates
    - Human microbiota and pathogens

Examples of utilisation

- Research aiming to discover specific genetic and/or biochemical characteristics
- Creation or improvement of genetic resources (for example cosmetic ingredients) to be used in manufacturing processes.
- Breeding programme to create a new plant variety based on landraces or naturally occurring plants.
- Genetic modification
- Research on a genetic resource leading to the isolation of a biochemical compound used as a new ingredient (active or not) incorporated into a biomedical product

Examples of no utilisation

- Processing of genetic resources as commodities
  - For example: the purchase of essential oils for further incorporation into cosmetics.
  - *However: if R&D occurs on genetic resources which originally entered the EU as commodities, such new use falls within the EU ABS Regulation.*
- Genetic resources as testing or reference tools
  - For example: using fluorescent proteins as a tool to track the dynamics of an ingredient.
- Planting and harvesting crops
- Collection management
- (Taxonomic) identification and characterisation

Utilisation of the plasmid: yes or no?

1. Using a vector (plasmid) to introduce DNA into an animal cell.
   - No utilisation of the plasmid: the plasmid is only used as a vehicle; no research or development takes place on the genetic and/or biochemical composition of the plasmid.

2. The DNA sequence of a vector (plasmid) is optimised to improve the expression level of a gene-of-interest.
   - Utilisation of the plasmid: research and development on the genetic and/or biochemical composition of the plasmid is done.

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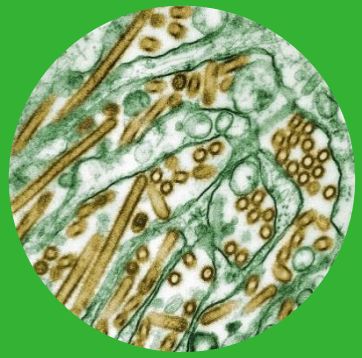


What to do as a user within the EU?

1. Check access rules of the provider country
   - ABS Clearing House (https://absch.cbd.int/)
   - National Focal Point (NFP) of the provider country
2. Exercise due diligence to ascertain which ABS conditions apply and comply with these
3. PIC (Prior Informed Consent): if required, obtain permission from the Competent National Authority (CNA) of the provider country

What to do as a user within the EU?

4. MAT (Mutually Agreed Terms): negotiate conditions with provider, and lay these down in a contract. Use the genetic resources only in accordance with these conditions.

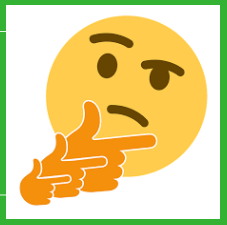
5. Carefully document the use (R&D) and keep all documentation for 20 years after the end of utilisation.

6. Submit a due diligence declaration (through https://webgate.ec.europa.eu/declare/) when you

   - receive external research funding, or
   - bring a product on the market

7. Pass on relevant information to subsequent users.

Some points of attention



- In the EU ABS Regulation, the user is responsible for compliance, not the supplier
  - *if genetic resources for R&D are bought from a trader, request access documentation*
- Some European countries have access legislation
  - *the obligations of the EU ABS Regulation may also apply to imports of genetic resources for R&D from these EU countries*
- USA is not foreseen to join the Nagoya Protocol
  - *EU ABS Regulation rules do not apply to US genetic resources (but only if they are really from USA)*
- ***National legislation in provider countries may go further than the EU ABS Regulation***
  - Check ABS Clearing-House website/NFP of provider country

Some recommendations

- Seek advice and help from local counterparts
- Find out if the genetic resource can be obtained
  - under a specialised international instrument (ITPGRFA, PIP-Framework)
  - from a collection included in the EU Register
- Try to conclude a framework agreement between your organisation and the provider country
- Keep documentation on genetic resources that do not fall under the EU ABS Regulation, to make plausible that these were legally accessed
- ***Look before you leap: take ABS aspects into account from the very start of the project***

More information

- ABS Clearing House website: (absch.cbd.int)
  - maintained by CBD/NP
  - country information (contact persons, laws)
- ABS website of the EU (http://ec.europa.eu/environment/nature/biodiversity/international/abs/legislation_en.htm)
  - information on EU rules
  - EU registers of collections and recognized 'best practices'
- Website ABS Focal Point (www.absfocalpoint.nl)
  - maintained by National Focal Point of NL
  - bilingual (Dutch/English)
  - information on rules and what to do

ABS Focal Point website

- www.absfocalpoint.nl
- Interactive help tool, newsletter
- Articles on:
  - Derivates (for example non-synthetic vectors, proteins, antibodies, plasmids)
  - Large-scale screening
  - Laboratory strains
  - Human microbiota/pathogens
  - Service providers
  - Testing and reference tools
  - and more

Thank you!

www.absfocalpoint.nl

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